

Patient Initials

Date of Birth

 - -

Site Number

Trial Number

To be completed 30 days after completion or discontinuation of OPTIMAL trial Treatment

10.1 CLINICAL ASSESSMENT

- Is patient alive? Yes No → please complete Notification of Death Form
↓
- Date of clinic visit?
- Weight (kg) .
- ECOG performance status 0 1 2 3 4
- Pregnancy Test (if applicable)

Result	<input type="checkbox"/>	→ Date	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1=Negative	<input type="checkbox"/>		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2=Positive	<input type="checkbox"/>								
3=Not applicable	<input type="checkbox"/>								
- Is patient on dialysis? Yes No → *If dialysis was started or stopped since patient's last trial visit please enter date:*
- Has the patient completed an EQ-5D-3L Quality of Life Questionnaire? Yes No *If no please give reason below:*

Date Questionnaire Completed:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
-------------------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------
- Have any Adverse Events or Adverse Reactions occurred since last trial visit?
 Yes No If yes please provide details in section 10.8
- A copy of Treatment Diary Card(s) attached?

Thalidomide -	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Already Returned	<input type="checkbox"/>
Dexamethasone -	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Already Returned	<input type="checkbox"/>

10.2 LOCAL LAB INVESTIGATIONS (Bone Marrow)

Tick samples collected

Date collected

<input type="checkbox"/> Bone Marrow Aspirate	→	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Bone Marrow Trepine	→	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

10.3 CENTRAL LAB INVESTIGATION (Birmingham)

Tick all samples collected:

Date Collected

Sample Sent?

Date Sent

<input type="checkbox"/> 2 ml bone marrow aspirate	→	<input type="text"/>	<input type="checkbox"/> Yes →	<input type="text"/>
			<input type="checkbox"/> No →	Reason for not sending: <input type="text"/>
<input type="checkbox"/> 5 ml blood (EDTA)	→	<input type="text"/>	<input type="checkbox"/> Yes →	<input type="text"/>
			<input type="checkbox"/> No →	Reason for not sending: <input type="text"/>
<input type="checkbox"/> 10 ml clotted blood	→	<input type="text"/>	<input type="checkbox"/> Yes →	<input type="text"/>
			<input type="checkbox"/> No →	Reason for not sending: <input type="text"/>
<input type="checkbox"/> 20 ml urine	→	<input type="text"/>	<input type="checkbox"/> Yes →	<input type="text"/>
			<input type="checkbox"/> No →	Reason for not sending: <input type="text"/>

Is sample from 24 hour collection? No Yes → Total vol. collected ml

Patient Initials

Date of Birth

 - -

Site Number

 0

Trial Number

 0

10.4 CENTRAL LAB INVESTIGATIONS (Oxford)

Tick all samples collected:

	Date Collected	Sample Sent?	Date Sent
<input type="checkbox"/> 5 ml bone marrow aspirate	→ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes →	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		<input type="checkbox"/> No →	Reason for not sending: <input type="text"/>
<input type="checkbox"/> 2 unstained slides bone marrow aspirate	→ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes →	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		<input type="checkbox"/> No →	Reason for not sending: <input type="text"/>

10.5 OPTIMAL TREATMENT SUMMARY

- Total number of treatment cycles completed:
- Date of last administration of treatment (dd/mm/yyyy)
- Patient's maximum response to OPTIMAL therapy using IMWG criteria (*choose one option only*)
 - 1=sCR
 - 2=CR
 - 3=VGPR
 - 4=PR
 - 5=SD
 - 6=PD
- Will the patient undergo PBSC mobilisation and harvest? 1=Yes
2=No, specify a reason:
- Please specify next line of therapy:

10.6 EFFICACY ASSESSMENT

Date of test (dd/mm/yyyy)

Specify Paraprotein type <input type="text"/>	Serum paraprotein <input type="checkbox"/> 1=Measureable, please complete result → <input type="text"/> <input type="text"/> <input type="text"/> (g/L)
	2=Immunofixation only
Specify Paraprotein type (if more than one type) <input type="text"/>	Serum paraprotein <input type="checkbox"/> 1=Measureable, please complete result → <input type="text"/> <input type="text"/> <input type="text"/> (g/L)
	2=Immunofixation only
Serum free light chain: Kappa <input type="checkbox"/>	1=Done, please complete result → <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> (mg/L)
	2=Not done
Serum free light chain: Lambda <input type="checkbox"/>	1=Done, please complete result → <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> (mg/L)
	2=Not done
Specify free light chain Kappa/Lambda ratio: <input type="checkbox"/> 1=Done: <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	2=Not done
24 hour urinary light chain (g/24hr) (Bence Jones protein) <input type="checkbox"/>	1=Present, please complete result: <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>
	2=Too faint to quantify
	3=Absent
	4= Not done
24 hour urinary light chain type (<i>please choose <u>one</u> only</i>): <input type="checkbox"/>	1=Kappa
	2=Lambda
	3= Not done

Patient Initials

--	--	--

Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
---	--	--

Trial Number

0		
---	--	--

10.7 Imaging (If clinically indicated, full skeletal survey not required)

X-rays (state area)		→	<input type="checkbox"/> 1=Normal <input type="checkbox"/> 2=No changes to baseline <input type="checkbox"/> 3=Additional changes to baseline <input type="checkbox"/> 4=Not done	Date of X-ray (dd/mm/yyyy)	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y						
MRI (state area)		→	<input type="checkbox"/> 1=Normal <input type="checkbox"/> 2=No changes to baseline <input type="checkbox"/> 3=Additional changes to baseline <input type="checkbox"/> 4=Not done	Date of MRI (dd/mm/yyyy)	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y						
CT Scan (state area)		→	<input type="checkbox"/> 1=Normal <input type="checkbox"/> 2=No changes to baseline <input type="checkbox"/> 3=Additional changes to baseline <input type="checkbox"/> 4=Not done	Date of CT scan (dd/mm/yyyy)	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y						
Other, please specify		→	<input type="checkbox"/> 1=Normal <input type="checkbox"/> 2=No changes to baseline <input type="checkbox"/> 3=Additional changes to baseline <input type="checkbox"/> 4=Not done	Date of test (dd/mm/yyyy)	<table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr></table>	d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y						

10.8 Adverse Events (AE) and Adverse Reactions (AR) (please provide details of all AE/ARs since end of treatment)

AE & AR key:

Severity Scale: 1. Mild, 2. Moderate, 3. Severe.

Outcome: 1. Resolved no sequelae, 2. Resolved with sequelae, 3. Death, 4. Continuing, 9. Not known.

Adverse Events (please use one line per AE)

AE Description (incl. CTCAE terms)	CTCAE Grade	Dates (dd/mm/yyyy)	Ongoing Y/N	Severity (use key above)	Outcome (use key above)																
		Start <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Stop <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			
		Start <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Stop <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			
		Start <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Stop <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			

Adverse Reactions (please use one line per AR)

AR Description (incl. CTCAE terms)	CTCAE Grade	Dates (dd/mm/yyyy)	Ongoing Y/N	Severity (use key above)	Outcome (use key above)																
		Start <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Stop <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			
		Start <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Stop <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			
		Start <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Stop <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			

Completed by:
(Print)

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Signature:

Date completed:

D	D	M	M	Y	Y	Y	Y

For Office use only

Date form received: _____

Date form entered: _____

Initials: _____